



Food and Drug Administration
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February 12, 2015

Intersurgical® Inc.
Mr. Michael Zalewski
Vice President, RA/QA/CS
417 Electronics Parkway
Liverpool NY, 13088

Re: K141087
Trade/Device Name: Product # 1331030S-Inter-Therm Mini Pediatric HMEF sterile
Product # 1332030S-Inter-Therm Mini Pediatric angled HMEF sterile
Regulation Number: 21 CFR 868.5260
Regulation Name: Filter, Bacterial, Breathing Circuit
Regulatory Class: II
Product Code: CAH
Dated: January 12, 2015
Received: January 13, 2015

Dear Mr. Zalewski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K141087

Device Name:

Product # 1331030S - Inter-Therm Mini Pediatric HMEF sterile

Product # 1332030S - Inter-Therm Mini Pediatric angled HMEF sterile

Indications For Use: The Inter-Therm Mini Pediatric HMEF Sterile is for use at the patient connections. The device is to be attached between the breathing circuit and patient connection. It is designed to reduce bacterial/viral transmission between the patient and equipment and to reduce the loss of patient heat and humidity. The filter is for single patient use only and therefore must be disposed of after a single patient usage and/or after its maximum duration of use at 24 hours. The device is a single use device that is required to be changed daily when used with devices (i.e. long-term ventilators) that are design to have patient body contact between 24 hours to < 30 days. The recommended pediatric weight range is 11 kg to 35 kg. The recommended tidal volume is 75 to 250 ml.

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5 510(k) Summary of Safety and Effectiveness

510K Submitter Address and Establishment Registration Number:

Registration Number: 1319447
Name: INTERSURGICAL INCORPORATED
Address: 417 Electronics Parkway
Liverpool, NY 13088
Date: February 2, 2015
Contact Person: Michael Zalewski – VP RA/QA/CS
Phone Number: 315-451-2900 X 202
Fax Number: 315-451-3696

Classification: 21 CFR 868.5260, Classification Name: Filter, Bacterial, Breathing Circuit, Classification Product Code: 73 CAH, Device Class: II, 510K Submission: Traditional.

Subject Device Trade Name:

Product # 1331030S - Inter-Therm Mini Pediatric HMEF sterile
Product # 1332030S - Inter-Therm Mini Pediatric angled HMEF sterile

Predicate Device:

The Inter-Therm Mini Pediatric HMEF sterile (Product # 1331030S) and the Inter-Therm Mini Pediatric angled HMEF sterile (Product #1332030S) are substantially equivalent to the Covidien 355U5430 DAR Infant - Pediatric Electrostatic Filter HME (Small – K941381- Hygroboy).

The 355U5430 DAR HMEF is a heat and moisture exchanger that allows for heated humidified air to be supplied to the patient when ventilated or under anaesthesia. The electrostatic filter prevents cross contamination between the patient and the breathing system. The HMEF is provided clean and is used in breathing systems in anesthesia and intensive care. The filter has an end tidal CO₂ sampling port for CO₂ monitoring. This port has a cap to block the port when it is not in use.

Description of Device:

Inter-Therm Mini Pediatric HMEF sterile (Product # 1331030S)

The Inter-Therm Mini Pediatric is a sterile HMEF used for passive humidification in pediatric patients under mechanical ventilation or anesthesia. The HMEF contains a HME paper and electrostatic filter pad incased in a plastic housing. The HME paper traps heat and moisture from the patient's exhaled air which is then returned in the inspiratory air to the patient. Therefore the patient receives heated, humidified air. The electrostatic filter pad prevents bacterial and viral cross-contamination between the breathing system and the patient.

Section 5 510(k) Summary of Safety and Effectiveness

The HMEF has an additional luer lock port for CO₂ monitoring with a retainable luer port cap to block the port when it is not in use. The HMEF has a 22F/15M connector at the machine end and a 22M/15F connector at the patient end.

Inter-Therm Mini Pediatric angled HMEF sterile (Product # 1332030S)

The Inter-Therm Mini Pediatric angled HMEF is a sterile HMEF used for passive humidification in pediatric patients under mechanical ventilation or anesthesia. The HMEF contains a HME paper and electrostatic filter pad incased in a plastic housing. The HME paper traps heat and moisture from the patient's exhaled air which is then returned in the inspiratory air to the patient. Therefore the patient receives heated humidified air. The electrostatic filter pad prevents bacterial and viral cross-contamination between the breathing system and the patient. The HMEF has an additional luer lock port for CO₂ monitoring with a retainable luer port cap to block the port when it is not in use. The HMEF has an angled 15M machine connector end, eliminating the need to use an elbow in the breathing circuit. The patient end is a straight 22M/15F connector.

Indications for Use:

The Inter-Therm Mini Pediatric HMEF Sterile is for use at the patient connections. The device is to be attached between the breathing circuit and patient connection. It is designed to reduce bacterial/viral transmission between the patient and equipment and to reduce the loss of patient heat and humidity. The filter is for single patient use only and therefore must be disposed of after a single patient usage and/or after its maximum duration of use at 24 hours. The device is a single use device that is required to be changed daily when used with devices (i.e. long-term ventilators) that are design to have patient body contact between 24 hours to < 30 days. The recommended pediatric weight range is 11 kg to 35 kg. The recommended tidal volume is 75 to 250 ml.

Technology Characteristics Summary

The intended use of the Intersurgical Inter-Therm Mini Breathing Filter and Heat and Moisture Exchanger is comparable to the referenced predicate device. The comparison of the data shows similar values for the key performance characteristics. Proposed devices show similar values for moisture return, resistance to flow, weight, tapers and filtration efficiency when compared to the legally marketed devices.

Non-clinical test results are submitted to confirm product safety and substantial equivalence to predicate device.

Section 5 510(k) Summary of Safety and Effectiveness
Device Comparison Table

| Characteristic Compared | Inter-Therm Mini Pediatric HMEF sterile 1331030S | Inter-Therm Mini Pediatric angled HMEF sterile 1332030S | DAR™ Infant – Pediatric Electrostatic Filter HME (Small) 355U5430 K941381 |
|-------------------------|--|--|---|
| Intended Use: | | | |
| Target population | Pediatric patients mechanically ventilated requiring heated humidified air | Pediatric patients mechanically ventilated requiring heated humidified air | Pediatric patients mechanically ventilated requiring heated humidified air |
| Indications for use | The Inter-Therm Mini Pediatric HMEF Sterile is for use at the patient connections. The device is to be attached between the breathing circuit and patient connection. It is designed to reduce bacterial/viral transmission between the patient and equipment and to reduce the loss of patient heat and humidity. The filter is for single patient use only and therefore must be disposed of after a single patient usage and/or after its maximum duration of use at 24 hours. The device is a single use device that is required to be changed daily when used with devices (i.e. long-term ventilators) that are design to have patient body contact between 24 hours to < 30 days. The recommended pediatric weight range is 11 kg to 35 kg. The recommended tidal volume is 75 to 250 ml. | The Inter-Therm Mini Pediatric HMEF Sterile is for use at the patient connections. The device is to be attached between the breathing circuit and patient connection. It is designed to reduce bacterial/viral transmission between the patient and equipment and to reduce the loss of patient heat and humidity. The filter is for single patient use only and therefore must be disposed of after a single patient usage and/or after its maximum duration of use at 24 hours. The device is a single use device that is required to be changed daily when used with devices (i.e. long-term ventilators) that are design to have patient body contact between 24 hours to < 30 days. The recommended pediatric weight range is 11 kg to 35 kg. The recommended tidal volume is 75 to 250 ml. | The HMEFs are used to provide heated humidified air and prevent cross contamination between the patient and breathing system. CO ₂ monitoring also possible. Only for use on pediatric patients and prescribed by a physician. It is a single patient use device and can be used for a maximum of 24 hours. |
| Where used | Hospital | Hospital | Hospital |
| Product Labeling | Inter-Therm HMEF Mini Pediatric | Inter-Therm HMEF Mini Angled Pediatric | DAR Infant – Pediatric Electrostatic Filter HME (Small) |
| Single Use or Reusable? | Single patient use for 24 hours | Single patient use for 24 hours | Single patient use for 24 hours |

Section 5 510(k) Summary of Safety and Effectiveness
Device Comparison Table

| Characteristic Compared | Inter-Therm Mini Pediatric HMEF sterile 1331030S | Inter-Therm Mini Pediatric angled HMEF sterile 1332030S | DAR™ Infant – Pediatric Electrostatic Filter HME (Small) 355U5430 K941381 |
|-------------------------------------|--|--|--|
| Design and Performance: | | | |
| Compressible Volume (ml) | 28 | 29 | 29.5 |
| Moisture Return (mg/L) | 30 @ 250ml tidal volume | 30 @ 250ml tidal volume | 33.3 @ 250ml tidal volume |
| Resistance to flow @ 30L/min (mbar) | 2.1 | 2.2 | 3.3 |
| Weight (g) | 20.0 | 18.4 | 21.3 |
| Minimum tidal volume (ml) | 75 | 75 | 75 (4) |
| Maximum tidal volume (ml) | 250 | 250 | 300 (4) |
| Type of filtration | Electrostatic | Electrostatic | Electrostatic |
| Filtration efficiency (%) | 99.98 BFE 99.95 VFE | 99.91 BFE 99.98 VFE | >99.99 |
| Tapers | PASS | PASS | ISO standard 15mm and 22mm |
| Ageing: 5 months | PASS | PASS | N/A |
| Ageing: 5 years | PASS | PASS | N/A |
| Materials: | | | |
| HMEF housing | Acrylonitrile Butadiene Styrene | Acrylonitrile Butadiene Styrene | - |
| Electrostatic filter | Polypropylene-based fiber blend | Polypropylene-based fiber blend | - |
| HME paper | Cellulose-based paper | Cellulose-based paper | - |
| Retainable luer port cap | Thermoplastic Elastomer with green color | Thermoplastic Elastomer with green color | - |
| Energy Used/Delivered: | Warm humidified air is extracted from expiratory air and delivered to the patient's inspiratory air. | Warm humidified air is extracted from expiratory air and delivered to the patient's inspiratory air. | Warm humidified air is extracted from expiratory air and delivered to the patient's inspiratory air. |
| Compatibility: | Designed for use with breathing systems, elbows, catheter mounts and CO2 monitoring lines | Designed for use with breathing systems, elbows, catheter mounts and CO2 monitoring lines | Designed for use with breathing systems, elbows, catheter mounts and CO2 monitoring lines |
| Biocompatibility: | | | |
| Sterility: | Sterile | Sterile | Clean |
| Standards Met: | | | |
| HME | ISO 9360-1:1992 | ISO 9360-1:1992 | ISO 9360-1:1992 |

Section 5 510(k) Summary of Safety and Effectiveness
Device Comparison Table

| Characteristic Compared | Inter-Therm Mini Pediatric HMEF sterile 1331030S | Inter-Therm Mini Pediatric angled HMEF sterile 1332030S | DAR™ Infant – Pediatric Electrostatic Filter HME (Small) 355U5430 K941381 |
|--------------------------------|---|--|--|
| Conical Connector ends | ISO 5356-1:2004 | ISO 5356-1:2004 | ISO 5356-1:2004 |
| Luer lock connectors | ISO 594-2:1998 | ISO 594-2:1998 | - |

Summary of Testing:

Nonclinical tests submitted to demonstrate substantial equivalence for moisture return, resistance to flow, weight, tapers and filtration efficiency. All materials used in the breathing filters have been evaluated according to tests outlined in ISO 10993-1 and meet the requirements of Bluebook Memo, General Program Memorandum G95-1 biocompatibility testing for cytotoxicity, sensitization, and irritation. The connectors meet the requirements of Anesthetic and respiratory equipment – conical connectors: Part 1: Cones and Sockets ISO 5356-1:2004, ISO 594-2:1998 Conical Fittings with a Luer Taper and Heat and Moisture Exchangers ISO 9360-1:1992.

Substantial Equivalence:

Intersurgical Incorporated has demonstrated that the proposed device is as safe and effective as the predicate device. It is considered to be substantially equivalent to the currently marketed predicate device which has been previously reviewed for market clearance by the FDA.

K141087
Premarket Notification [510(k)] Number